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09/521,545	03/09/2000	Dale G. Swan	9896.145.0	2248

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EXAMINER
CELSA, BENNETT M

ART UNIT	PAPER NUMBER
1627	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/521,545	Swan et al.
Examiner	**Art Unit**
Bennett Celsa	1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above, claim(s) *11-28* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *4 & 5*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Status of the Claims

Claims 1-28 are currently pending.

Claims 1-10 are under consideration to the extent they read on the elected invention.

Claims 11-28 are withdrawn from further consideration as being drawn to a nonelected invention.

Election/Restriction

1. Applicant's election of Group I (claims 1-10) in Paper No. 9 (dated 7/13/01) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Applicant's further election of the compound CH2=CH(CH3)-C(=O)-O-CH2- CH-O-CH2 in Paper No. 13 (dated 10/15/01 which reads on claims 1-10 is acknowledged.. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 11-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Priority

4. Applicant is claiming 35 USC 120 priority of the present application (09/521,545 filed 3/9/2000) as a CIP application to:

a. 09/227,913 (1/8/99) or

b. 08/940,213 (9/30/97).

It is noted that the presently claimed invention (e.g. claims 1-10) does not comply with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *In re Ahlbrecht*, 168 USPQ 293 (CCPA 1971).

E.g. the newly claimed invention constitutes new matter (e.g. polyepoxide containing reagent composition) which is not supported by either of the prior applications in items a. or b. above.

Accordingly, for purposes of prior art, present claims 1-10 are denied 35 USC 120 priority; and thus are afforded the date 3/9/2000 for purposes of prior art.

Specification

5. The disclosure is objected to because of the following informalities: .

6. The use of the trademark "NucleoLink TM" (e.g. page 2); "Reacti-Bind TM"(e.g. page 3); "DNA-BIND TM" (e.g. page 3); has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claim 1, the term "polymeric backbone *adapted to* be covalently attached..." and "pendent epoxide groups *adapted to* form covalent bonds ..." both lack metes and bounds with respect to the adaptations (or derivations) of polymeric and epoxide structure encompassed by the claimed invention and the resulting polymeric and epoxide structure.

B. Claims 1-10 are confusing as to whether the "Reagent composition" encompasses the (adapted) polymer with pendent (adapted)epoxide groups alone or whether the composition further comprises a "surface".

C. In claims 2- 4 (line 1) and 8 (line 3), the term "the reagent" lacks clear antecedent basis.

D. In claim 2, line 3, "group glycidyl" should be --- group *consisting of* glycidyl --- in order to recite a proper Markush listing. See MPEP 2173.05(h).

E. The term "noninterfering radical" in claim 3 is a relative term which renders the claim indefinite. The term "noninterfering radical" is not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree of "noninterference", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

F. Claim 3 is indefinite since a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex*

parte Hasche, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation "noninterfering radical", and the claim also recites a preferred Markush group (e.g. "preferably selected") which is the narrower statement of the range/limitation.

G. The term "*latent reactive* groups comprising photoreactive groups" in claim 8 is a relative term which renders the claim indefinite. The term "latent reactive groups" is not defined by the claim, nor does the specification provide a standard for ascertaining the requisite degree of "latent reactivity", and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kalal et al. US Pat. No. 4,332,694 (1/82).

Kalal et al. disclose epoxide containing polymers (e.g. see abstract; col. 2 (especially lines 1-18 and 51-65; poly 2,3 epoxypropyl acrylate: see examples; patent claims) which anticipates a composition within the scope of present claim 1, since intended use limitations are not afforded patentable weight. However, the intended use limitation of the use of the epoxy containing polymers to "attach a target molecule" is nevertheless taught by the reference (e.g. see col. 1, lines 55-65). Similarly, although the method of making the polymer is not relevant to patentability if the prior art teaches a composition within the scope, the Kalal et al. reference nevertheless makes in epoxide containing polymers utilizing monomers within the scope of the presently claimed invention (e.g. see col. 2; examples and patent claims). The further attachment

of "photoreactive groups" is suggested (e.g. diazotization: col. 39-45) and specifically taught (e.g. see examples, especially example 1: and derivation with azobisisobutyronitrile compound). The Kalal et al. epoxide containing polymer can be (and is) adapted to be covalently attached to a "surface of a substrate" (e.g. inorganic porous materials such as glass, silica , asbestos etc.: see col. 2 and examples).

12. Claims 1 is rejected under 35 U.S.C. 102(a,b) as being anticipated by Nagasawa et al., J. Applied Biochemistry Vol. 7, pages 430-437 (1985).

Nagasawa et al. teaches a composition comprising a polymeric backbone comprised of Sepharose (e.g. a polymer i.e. a polysaccharide polymer) with "one or more pendent epoxide groups" (e.g. oxirane groups) which covalently bind "target molecules" (e.g. DNA). It is noted that intende use claim language (e.g. the use of the composition as a reagent; and covalent attachment to a surface) is not afforded patentable weight in a compound/composition claim. Alternatively, the reference meeting of the compositional requirements (e.g. polymer with epoxide binding DNA pendent groups) would render the intended use limitations inherent.

13. Claims 1-3 and 5-8, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kalal et al. US Pat. No. 4,332,694 (1/82) and Shi et al. US 5,919,626 (7/99: filed 6/97)..

Kalal et al. disclose epoxide containing polymers (e.g. see abstract; col. 2 (especially lines 1-18 and 51-65; poly 2,3 epoxypropyl acrylate: see examples; patent claims) which anticipates a composition within the scope of present claim 1, since intended use limitations are not afforded patentable weight. However, the intended use limitation of the use of the epoxy containing

polymers to "attach a target molecule" is nevertheless taught by the reference (e.g. see col. 1, lines 55-65). Similarly, although the method of making the polymer is not relevant to patentability if the prior art teaches a composition within the scope, the Kalal et al. reference nevertheless makes in epoxide containing polymers utilizing monomers within the scope of the presently claimed invention (e.g. see col. 2; examples and patent claims). The further attachment of "photoreactive groups" is suggested (e.g. diazotization: col. 39-45) and specifically taught (e.g. see examples, especially example 1: and derivation with azobisisobutyronitrile compound). The Kalal et al. epoxide containing polymer can be (and is) adapted to be covalently attached to a "surface of a substrate" (e.g. inorganic porous materials such as glass, silica , asbestos etc.: see col. 2 and examples).

The Kalal et al. reference composition differs from the presently claimed invention by failing to teach the target being a nucleic acid to directly attached underivatized nucleic acid and the use of silanized glass containing epoxides.

However, the Shi et al. Reference teaches that an epoxy groups can directly bind unmodified nucleic acids as targets; and additionally, the preferential use of polymerized epoxides on silanized glass surfaces.

Accordingly, one of ordinary skill in the art would be motivated to modify the Kalal et al. Reference method to employ nucleic acids as targets for attachment to polymeric epoxides as disclosed in Kalal et al. And the further use of silanized glass for the benefits obtained therefrom (e.g promote N.A. attachment) as taught by the Shi et al. Reference.

Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Kalal et al. reference composition to utilize unmodified nucleic acids as target compounds and silanized glass for the benefits obtained therefrom as taught by the Shi reference.

14. Claims 1 and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. US Pat. No. 5,942,555 (8/99: filed 3/96) and Shi et al. US Pat. No. 5,919,626 (7/99: filed 6/97).

Swanson et al. teach chain transfer agents (e.g. Yi-X-SH: see col. 5) that comprise:

a. Y is an organic radical(s) comprising one or more photoactivatable groups (e.g. aryl ketones, benzophenones are preferred: see col. 5);

b. X is an optional spacer (see col. 6-7); and

c. SH.

The Swanson photoactivatable chain-transfer groups can be used in a variety of polymerization (including copolymerization: see col. 13, lines 38-50)) reactions that employ chain-transfer agent (e.g. see col. 7). Accordingly, the chain transfer groups can be used as photopolymers, including the simultaneous or sequential attachment of the polymer to a support surface (e.g. see col. 13, especially lines 1-10 and lines 50-top of col. 14), including *silylated surfaces of glass*, ceramic or metal as well as plastics (e.g. see col. 13, lines 25-38) (emphasis provided). The Swanson photopolymers can be used to "immobilize desired molecules onto the surface" (e.g. see col. 14,

lines 5-11) including the attachment of protein and nucleic acid targets (e.g. see Examples, especially examples 14 and 33-35). However, it is noted that attachment of the nucleic acids to the chain transfer groups (e.g. SH) of the Swanson photopolymer *requires that the oligonucleotide be modified* (e.g. see Example 35 requiring thiol (SH) nucleic acid modification) in order to covalently immobilize the oligonucleotide to the Swanson photopolymer (emphasis provided). However, it is also noted that the reference specifically discloses that *chain groups other than SH can be utilized* (e.g. see Abstract; col. 7, lines 10-27 (emphasis provided).

The Swanson reference reagent composition (e.g. photopolymer) differs from the presently claimed invention by:

a. utilizing epoxide groups instead of SH groups to attached the target (e.g oligonucleotide);

b. utilizing silanized glass instead of silylated glass as the treated surface.

However, the Shi et al. Patent reference teaches that organosilanes (e.g. silanization) can be used to "tailor surfaces" (especially glass) with mercapto (SH) and/or epoxy groups" (e.g. see col. 5, lines 1-5) in order to permit the covalent attachment of *"unmodified"* oligonucleotides (e.g. see col. 7, especially lines 25-40) (emphasis provided).

Accordingly, one of ordinary skill in the art would be motivated to modify the Swanson reference method of attaching target groups (e.g. oligonucleotides) to utilize silanized surfaces (e.g. glass) and additionally utilize epoxy groups alone or in conjunction with SH groups to bind targets (especially oligonucleotides) in order to permit the attachment of the target (e.g. oligonucleotide) without derivation of the target, with a reasonable expectation of success since

the Swanson reference composition and means of attachment of target compounds utilizes SH or other groups in the alternative to bind target compounds and uses similar (and in some cases identical) substrates (e.g. glass) for attachment of the reagent composition.

Thus it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Swanson reference reagent and method of attaching a target (e.g oligonucleotide) by modifying the Swanson photopolymer composition to substitute epoxy groups (or epoxy and SH groups) for the SH groups disclosed in Swanson for use in applying to silanized surfaces (e.g. glass) in order to realize the benefits therefrom such as the attachment of targets (e.g. oligonucleotides) without the need to modify the target (e.g. oligonucleotide) as taught by the Shi et al. Patent reference.

15. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Swanson et al. and Shi et al. as applied to claims 1 and 5-10 above, and further in view of Kalal et al. US Pat. No. 4,332,694(6/82).

The above obviousness rejection is hereby incorporated by reference in its entirety.

The Swanson and Shi et al. combined teaching differs from the presently claimed invention by failing to specifically teach the use of (allyl) glycidyl / (meth)acrylate/glycidyl vinyl monomers for making polymeric reagents.

However, Kalal et al. disclose epoxide containing polymers (e.g. see abstract; col. 2 (especially lines 1-18 and 51-65; poly 2,3 epoxypropyl acrylate: see examples; patent claims). Although the method of making the polymer is not relevant to patentability if the prior art teaches

a composition within the scope, the Kalal et al. reference nevertheless makes epoxide containing polymers utilizing monomers within the scope of the presently claimed invention including the use of (allyl) glycidyl / (meth)acrylate/glycidyl vinyl monomers (e.g. see col. 2; examples and patent claims). The further attachment of "photoreactive groups" is suggested (e.g. diazotization: col. 39-45) and specifically taught (e.g. see examples, especially example 1: and derivation with azobisisobutyronitrile compound). It is further noted that the Kalal et al. epoxide containing polymer can be (and is) adapted to be covalently attached to a "surface of a substrate" (e.g. inorganic porous materials such as glass, silica , asbestos etc.: see col. 2 and examples).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to employ the use of known monomers for making epoxylated resins as taught by Kalal et al. in the combined teaching of the Shi et al. and Swanson et al. References with a reasonable expectation of success.

General information regarding further correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Celsa whose telephone number is (703) 305-7556.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat (art unit 1627), can be reached at (703)308-0570.

Any inquiry of a general nature, or relating to the status of this application, should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Bennett Celsa (art unit 1627)
January 9, 2002

BENNETT CELSA
PRIMARY EXAMINER